

§ 21.605

the FAA denies the application and notifies the applicant.

[Docket No. FAA-2006-25877, Amdt. 21-92, 74 FR 53392, Oct. 16, 2009, as amended by Doc. No. FAA-2018-0119, Amdt. 21-101, 83 FR 9169, Mar. 5, 2018]

§ 21.605 Organization.

(a) Each applicant for or holder of a TSO authorization must provide the FAA with a document—

(1) Describing how its organization will ensure compliance with the provisions of this subpart;

(2) Describing assigned responsibilities, delegated authorities, and the functional relationship of those responsible for quality to management and other organizational components; and

(3) Identifying an accountable manager.

(b) The accountable manager specified in paragraph (a) of this section must be responsible within the applicant's or production approval holder's organization for, and have authority over, all production operations conducted under this part. The accountable manager must confirm that the procedures described in the quality manual required by § 21.608 are in place and that the production approval holder satisfies the requirements of the applicable regulations of subchapter C, Aircraft. The accountable manager must serve as the primary contact with the FAA.

[Doc. No. FAA-2013-0933, Amdt. 21-98, 80 FR 59032, Oct. 1, 2015]

§ 21.607 Quality system.

Each applicant for or holder of a TSO authorization must establish a quality system that meets the requirements of § 21.137.

§ 21.608 Quality manual.

Each applicant for or holder of a TSO authorization must provide a manual describing its quality system to the FAA for approval. The manual must be in the English language and retrievable in a form acceptable to the FAA.

§ 21.609 Location of or change to manufacturing facilities.

(a) An applicant may obtain a TSO authorization for manufacturing facilities

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located outside of the United States if the FAA finds no undue burden in administering the applicable requirements of Title 49 U.S.C. and this subchapter.

(b) The TSO authorization holder must obtain FAA approval before making any changes to the location of any of its manufacturing facilities.

(c) The TSO authorization holder must immediately notify the FAA, in writing, of any change to the manufacturing facilities that may affect the inspection, conformity, or airworthiness of its product or article.

§ 21.610 Inspections and tests.

Each applicant for or holder of a TSO authorization must allow the FAA to inspect its quality system, facilities, technical data, and any manufactured articles and witness any tests, including any inspections or tests at a supplier facility, necessary to determine compliance with this subchapter.

§ 21.611 Issuance.

If the FAA finds that the applicant complies with the requirements of this subchapter, the FAA issues a TSO authorization to the applicant (including all TSO deviations granted to the applicant).

§ 21.613 Duration.

(a) A TSO authorization or letter of TSO design approval is effective until surrendered, withdrawn, or otherwise terminated by the FAA.

(b) If a TSO is revised or canceled, the holder of an affected FAA letter of acceptance of a statement of conformance, TSO authorization, or letter of TSO design approval may continue to manufacture articles that meet the original TSO without obtaining a new acceptance, authorization, or approval but must comply with the requirements of this chapter.

§ 21.614 Transferability.

The holder of a TSO authorization or letter of TSO design approval may not transfer the TSO authorization or letter of TSO design approval.

§ 21.616 Responsibility of holder.

Each holder of a TSO authorization must—

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(a) Amend the document required by § 21.605 as necessary to reflect changes in the organization and provide these amendments to the FAA.

(b) Maintain a quality system in compliance with the data and procedures approved for the TSO authorization;

(c) Ensure that each manufactured article conforms to its approved design, is in a condition for safe operation, and meets the applicable TSO;

(d) Mark the TSO article for which an approval has been issued. Marking must be in accordance with part 45 of this chapter, including any critical parts;

(e) Identify any portion of the TSO article (e.g., sub-assemblies, component parts, or replacement articles) that leave the manufacturer's facility as FAA approved with the manufacturer's part number and name, trademark, symbol, or other FAA approved manufacturer's identification;

(f) Have access to design data necessary to determine conformity and airworthiness for each article produced under the TSO authorization. The manufacturer must retain this data until it no longer manufactures the article. At that time, copies of the data must be sent to the FAA;

(g) Retain its TSO authorization and make it available to the FAA upon request; and

(h) Make available to the FAA information regarding all delegation of authority to suppliers.

§ 21.618 Approval for deviation.

(a) Each manufacturer who requests approval to deviate from any performance standard of a TSO must show that factors or design features providing an equivalent level of safety compensate for the standards from which a deviation is requested.

(b) The manufacturer must send requests for approval to deviate, together with all pertinent data, to the FAA. If the article is manufactured under the authority of a foreign country or jurisdiction, the manufacturer must send requests for approval to deviate, together with all pertinent data, through

the civil aviation authority of that country or jurisdiction to the FAA.

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§ 21.619 Design changes.

(a) *Minor changes by the manufacturer holding a TSO authorization.* The manufacturer of an article under an authorization issued under this part may make minor design changes (any change other than a major change) without further approval by the FAA. In this case, the changed article keeps the original model number (part numbers may be used to identify minor changes) and the manufacturer must forward to the FAA, any revised data that are necessary for compliance with § 21.603(b).

(b) *Major changes by the manufacturer holding a TSO authorization.* Any design change by the manufacturer extensive enough to require a substantially complete investigation to determine compliance with a TSO is a major change. Before making a major change, the manufacturer must assign a new type or model designation to the article and apply for an authorization under § 21.603.

(c) *Changes by persons other than the manufacturer.* No design change by any person (other than the manufacturer who provided the statement of conformance for the article) is eligible for approval under this part unless the person seeking the approval is a manufacturer and applies under § 21.603(a) for a separate TSO authorization. Persons other than a manufacturer may obtain approval for design changes under part 43 or under the applicable airworthiness regulations of this chapter.

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§ 21.620 Changes in quality system.

After the issuance of a TSO authorization—

(a) Each change to the quality system is subject to review by the FAA; and

(b) The holder of the TSO authorization must immediately notify the FAA,